United States Department of Agriculture
Agricultural Marketing Service
STOP 0268 – Room 4008-S
1400 Independence Avenue, SW.
Washington, D.C. 20250-0200

MEMORANDUM

DATE: March 9, 2006

TO: National Organic Standards Board

FROM: Valerie Frances
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SUBJECT: Recommended Framework to Further Clarify the Definition of Synthetic

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This memorandum recommends a framework for determining whether or not a substance is synthetic or nonsynthetic for purposes of carrying out the Organic Food Production Act (OFPA) and its implementing regulations (i.e., the NOP rule). The purpose of this framework is to clarify and refine the meaning of "synthetic" as defined by the OFPA and the NOP rule, as the term pertains to consideration of substances for inclusion on the National List of Allowed and Prohibited Substances (National List). This framework is based on the NOSB Formal Recommendation of August 17, 2005, titled "NOSB guidance for the review of synthetic and non-synthetic substances."

Section 1 provides introductory language that makes it clear why additional guidance is needed to supplement the OFPA definition of "synthetic." Section 2 provides relevant existing definitions and presents proposed new definitions. Section 3 discuses each of the proposed new definitions. In particular, the discussion explains why each newly defined term is included and how the new term relates to the overall meaning of "synthetic." If uncertainties arise in applying these terms in the future, the discussion section may provide guidance on the underlying intent of the definitions.

1. Introduction

One of the primary determinants of whether a food can be considered "organic" is whether it contains or was produced with "synthetic" substances. The OFPA and the NOP rule define "synthetic," and the NOP and NOSB apply this definition in various regulatory and policy contexts such as the consideration of substances for inclusion on the National List. In some cases, the NOSB and NOP have encountered uncertainties in applying the definition of "synthetic" to specific substances because some phrases in the definition have been found to be ambiguous in certain citations. The framework presented below resolves these ambiguities.

2. Definitions

2.1 Relevant Existing Definitions

The terms below are defined in the OFPA and the NOP rule. The definition of "synthetic" is included below because the purpose of this document is to refine the intended meaning of "synthetic" as it is applied to substances petitioned for addition or prohibition to the National List. The existing definitions of "nonsynthetic" and "processing" are included below because these terms are relevant to the discussion of newly defined terms.

- **Synthetic** – "A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes." (7 CFR 205.2)

- **Nonsynthetic (natural)** – "A substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502(21) of the [OFPA] (7 U.S.C. 6502(21)). Nonsynthetic is used as a synonym for natural as the term is used in the [OFPA]." (7 CFR 205.2)

- **Processing** – "Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing and includes the packaging, canning, jarring, or otherwise enclosing food in a container." (7 CFR 205.2)

2.2 Proposed New Definitions

- **Natural Source** – Naturally occurring mineral, plant, or animal matter used to obtain nons-ynthetic inputs for organic production or handling.

- **Extraction** – The removal of a substance from a natural source by any chemical (e.g., solvent extraction, chemical precipitation) or physical (e.g., mechanical pressure, centrifugation, heating) manner and with any substance.

- **Formulation (manufacturing) –** The manufacture of an agricultural or handling input that is derived from a substance extracted from a natural source or produced by a naturally occurring biological process. Formulation is a synonym for manufacturing as the term is used in the OFPA definition of "synthetic."
- **Substance –** An element, molecular species, or chemical mixture that processes a distinct identity (e.g., having a separate Chemical Abstract Service (CAS) number, Codex International Numbering System (INS) number, or FDA or other agency standard identity).

- **Naturally occurring biological process** – Chemical changes that occur in living cells or due to the action of products of living organisms, such as enzymes.

- **Chemical change** – An occurrence whereby the identity of a substance is modified, such that the resulting substance possesses a different distinct identity. (See related definition of "substance.")

3. Discussion

This section provides the basis and rationale for the definitions proposed in Section 2.2. In addition, this section explains how the newly defined terms are intended to affect the meaning of "synthetic" (e.g., as it is applied to substances petitioned for addition or prohibition to the National List).

3.1 Natural Source

The term "natural source" is not used in the definition of "synthetic." However, the proposed definition of "natural source" is derived from and consistent with the definitions of "synthetic" and "nonsynthetic" in the OFPA and NOP rule. The term "natural source" is used in other newly proposed definitions.

For consistency with the OFPA and NOP rule, the definition does not include microbiological or fungal matter. The NOSB should evaluate whether microbiological or fungal matter should be included in the definition.

3.2 Extraction

"Extraction" is defined to clarify its meaning as used in the OFPA definition of "synthetic." The definition clarifies the differences between extraction, formulation, and processing.

An extracted substance is nonsynthetic if:

- It is extracted from a natural source;

- It is not chemically changed into a different substance during extraction;

- The process of extraction does not alter the substance into a chemical form (e.g., isomer) that does not occur in nature;

- Important functional properties (e.g., nutritional value) of the substance are not altered by extraction; and

- It is not contaminated with a significant level of a synthetic substance that is not on the National List. "Significant level" in this context is an amount capable of producing a functional or technical effect.

Chemicals used in extraction do not necessarily have to be nonsynthetic.

3.3 Formulation (Manufacturing)

"Formulation" is defined to clarify the meaning of the term "formulation or manufacturing" as used in the OFPA definition of "synthetic." The definition also clarifies the differences between extraction, formulation, and processing.

A formulated substance is nonsynthetic if:

- It contains only:
  - Nonsynthetic substances
  - Synthetic substances on the National List

- The process of formulation does not transform an ingredient into a different substance via a chemical change, with the exception of substances formed via a naturally occurring biological process.

- The process of formulation results in the retention of important functional properties (e.g., nutritional value) of active ingredients.

3.4 Substance

Minerals and inorganic substances generally can be identified by an exact molecular weight and chemical formula. Large, complex biochemicals (e.g., proteins, polysaccarides, lipids) are generally identified according to their carbon-based structure units and attached functional groups. Large organic chemicals often cannot be described by exact atomic composition or molecular weight. For example, the functional groups or the number of monomers in a natural polymer can vary without changing identity of the whole molecule. The definition of "substance" recognizes that a substance does not necessarily have a uniform and static atomic or molecular composition. Therefore, substances are distinguished from one another based on identities assigned by independent naming or regulatory bodies, such as the Chemical Abstract Society (CAS). Such identities may be based on chemical, technical, or functional properties.

Any synthetic substance for use in crops and livestock, and any nonorganic substance for use in food processing, must be a separate entry on the National List.

3.5 Naturally Occurring Biological Process

Substances created by naturally occurring biological processes are not considered synthetic. For example, lactic acid is considered a nonsynthetic substance when it has been formulated via the fermentation of lactose (milk sugar) by the bacterium *Lactobacillus*.

3.6 Chemical Change

A chemical change is intended to mean an event in which one substance becomes one or more a difference substances. A chemical change may result from specific types of chemical reactions such as:

(1) Addition or combination reactions;
(2) Decomposition reactions;
(3) Displacement reactions; and
(4) Protein configuration changes.

The occurrence of these types of reactions does not necessarily result in a chemical change, however, because it is possible for the atomic composition or configuration of a substance to change without a change in the identity of the substance. This is particularly true for large, complex biomolecules or for substances that are mixtures of various chemical species. Therefore, the occurrence of a chemical change is identified based on the identity and empirical properties of the starting and resulting substances.

In cases where the starting and/or resulting chemicals or chemical mixtures have not previously been assigned recognized identities (e.g., CAS numbers) or where the occurrence of a chemical change is uncertain for other reasons, NOSB and NOP may consider additional factors such as:

- Changes in the technical or functional properties (e.g., nutritional value, flavor, efficacy for an intended use) of the chemicals involved;
- Whether the chemicals involved are found in natural sources;
- Whether naturally occurring biological processes are involved;
- The role of synthetic substances, if any; and
- The extent to which chemical reactions of the types listed above are involved.